

### REMARKS

Favorable reconsideration of this application is requested in view of the above amendments and the following remarks. Claims 16-43 are pending. The non-elected claims have been canceled without prejudice or disclaimer; a divisional application is pending. The pending claims have been revised to remove the “means” language. The presence of “means” in the original claims was from the translation of the original Japanese international stage filing, and did not reflect an intent by the inventors to invoke the provisions of 35 USC 112, sixth paragraph.

Claims 16, 17, 19, 21-24, 28-33, 35, 37 and 38 have been rejected as obvious over Schibli in view of Taniike and Lin. Applicants respectfully traverse this rejection. Applicants note that the PTO 892 form incorrectly lists the Schibli reference as EP 1167532, and request that this be corrected to EP 1167538.

The rejection concludes at pages 5-6 that limitations in claim 16 concerning the characterization of electrodes as working electrodes and counter electrodes, and measurement of Hct value in the second analysis portion can be disregarded. Applicants respectfully dispute this. While a mere statement of intended use may have relatively low relevance to patentability, the limitations of claim 16 at issue here reflect far more than intended use and have clear and significant implications for the apparatus itself. It is well-understood that a working electrode and counter electrode play specific and different roles in a sensor, with the counter electrode being the electrode that serves as reference when applying a voltage. The identification of particular electrodes as working or counter in a particular analysis portion clearly defines the relationship between those electrodes in that particular analysis portion. The fact that one of the electrodes may be capable of performing another role relative to other electrodes in another analysis portion in no way changes the relationship between the electrodes specified for that particular analysis portion. Likewise, the indication that the second analysis portion measures the Hct value in claim 16 has clear implications as to the nature and content of that analysis portion, and reflects far more than an intended use. It has long been held that it is perfectly acceptable to define a product in terms of what it “does” as well as or instead of what it “is”. In re Hallman, 210 USPQ 608, 611, (citing, inter alia, In re Echerd, 176 USPQ 321 and In re

Swinehart, 169 USPQ 226), and Ex parte Bylund, 217 USPQ 492, 498. Therefore the rejection errs in disregarding these aspects of claim 16.

Moreover, Schibli teaches a sensor for glucose (and some other non-hematocrit blood components) in which a paste containing enzyme and mediator is applied to both electrodes in what the rejection defines as an analysis portion. The rejection then cites Taniike as suggesting that mediator could be provided on a counter electrode but not a working electrode as required by the second analysis portion of claim 16. As Taniike is directed to a glucose sensor and like Schibli does not contemplate a hematocrit analysis portion, there is nothing to suggest that Taniike's teachings would in any way be applicable to electrodes in an analysis portion that conducts analysis of hematocrit. Lin's teaching that hematocrit can be measured by a sensor in no way suggests that Taniike's teachings could be applied to Schibli and the resulting product converted to a hematocrit analyzer, particularly in view of the fact that Lin uses a common reaction film 4 for both electrodes.

Finally, the rejection justifies the combination of Taniike with Schibli by stating at page 5 "Therefore it would be obvious to [sic- a] person of ordinary skill in the art at the time of the invention to dispose mediator only on the counter electrode as taught by Taniike in the second electrode system of Schibli because mediator being primarily on the counter electrode prevents the reaction occurring at the counter electrode and thus preventing reaction at the electrode from becoming a rate determining step at high sample concentration to obtain linear response current (see paragraph [0050])." Applicants respectfully submit that this analysis fails to consider the actual teachings of Taniike and reflects the improper use of hindsight. Taniike teaches in paragraph [0050] that the problem to be avoided is that of the enzyme reaction proceeding at the counter electrode. That is, the presence of the enzyme with mediator at the counter electrode is undesirable. Therefore, one of ordinary skill properly considering the Taniike disclosure as a whole would conclude that the advantageous effects are obtained by isolating the enzyme from the counter electrode. One of ordinary skill applying this teaching to Schibli, where the enzyme and mediator are applied to both electrodes, would conclude that the advantages would be achieved by excluding the enzyme from the counter electrode, not by excluding the mediator from the working electrode. Therefore, the reference teachings do not support the rejection's asserted justification for the combination.

In view of the above, Applicants respectfully request that the rejection over Schibli, Taniike and Lin be withdrawn. Claims 25-27, 34, 39, 40-42 and 43 have been rejected over these three references in combination with various additional references. These rejections are erroneous for at least the same reasons and should be withdrawn. Applicants are not conceding the correctness of these rejections.

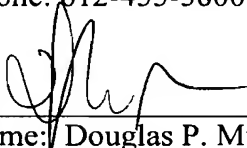
Claims 16, 18, 20 and 36 have been rejected as obvious over Yoshioka in view of Taniike and Lin. Taniike and Lin are cited for reasons similar those in the rejection discussed above. Yoshioka teaches a device in which a common reaction layer 5 is provided for the working and counter electrodes (col. 5, lines 23-29). Therefore, Yoshioka is no more relevant for purposes of this rejection than Schibli was in the rejection discussed above, and the same distinctions apply. The present rejection is erroneous for the reasons discussed above and should be withdrawn.

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.

Respectfully submitted,

HAMRE, SCHUMANN,  
MUELLER & LARSON, P.C.  
P.O. Box 2902  
Minneapolis, MN 55402-0902  
Phone: 612-455-3800

Date: December 3, 2010

By   
Name: Douglas P. Mueller  
Reg. No. 30,300  
Customer No. 53148

DPM/gmd